



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Martin A. Cheever and Mary L. Disis
Application No. : 09/167,516
Confirmation No. : 1422
Filed : October 06, 1998
For : COMPOUNDS FOR ELICITING OR ENHANCING IMMUNE REACTIVITY TO HER-2/neu PROTEIN FOR PREVENTION OR TREATMENT OF MALIGNANCIES IN WHICH THE HER-2/neu ONCOGENE IS ASSOCIATED

Examiner : Karen A. Canella, Ph.D.
Art Unit : 1642
Docket No. : 920010.448C8

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner:

I, Martin A. Cheever, hereby declare as follows:

1. Mary L. Disis and I are coinventors of the subject matter described in the above-identified patent application (hereinafter referred to as "subject application").

2. I hold an M.D. and was employed at the time the subject application was filed by the University of Washington where I held the position of Professor of Medicine, Division of Medical Oncology. I am presently employed by Corixa Corporation of Seattle, Washington.

3. I have been involved in immunology for over 25 years and I have authored or coauthored about 100 publications in this field. My research specialty is immunology related to cancer.

4. I am a co-author of the article appended hereto: Foy et al., Vaccine 19:2598-2606, 2001 (hereinafter referred to as "the article").

5. Figure 1 at page 2600 of the article shows that vaccination of mice with a plasmid expressing ICD polypeptide (intracellular domain of HER-2/neu protein) is effective to prevent growth of HER-2/neu tumor.

6. The results shown in Figure 1 of the article necessarily mean that sufficient polypeptide is expressed by the plasmid DNA encoding ICD polypeptide to generate an efficacious immune response.

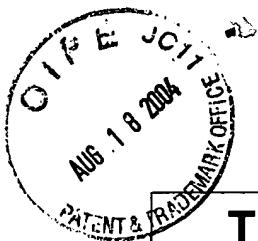
7. The sentence beginning at the end of page 2603 and completed at the top of page 2605 of the article states: "Taken together, these data provide strong evidence to suggest that protective immunity to Her-2/neu can be elicited by vaccination, demonstrating its utility as a cancer vaccine target."

8. Thus, the results presented in the article confirm the teachings of the subject application that administration to a warm-blooded animal of DNA or plasmid expressing ICD polypeptide of HER-2/neu protein achieves transient expression to the extent necessary to generate an efficacious immune response.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that the making of willfully false statements and the like is punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and may jeopardize the validity of any patent issuing from this patent application.

Dated this 31 day of July, 2004.

Martin A. Cheever
Martin A. Cheever



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08-19-04

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1642

TRANSMITTAL FORM

(To be used for all correspondence after initial filing)

Application Number	09/167,516
Filing Date	October 06, 1998
First Named Inventor	Martin A. Cheever
Art Unit	1642
Examiner Name	CANELLA, Karen A.
Attorney Docket No.	920010.448C8

ENCLOSURES (check all that apply)

- | | |
|---|--|
| <input type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) |
| <input type="checkbox"/> Fee Attached | <input type="checkbox"/> Request for Corrected Filing Receipt |
| <input type="checkbox"/> Amendment/Response | <input type="checkbox"/> Licensing-related Papers |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition |
| <input checked="" type="checkbox"/> 1.132 Declaration | <input type="checkbox"/> Petition to Convert to a Provisional Application |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Declaration |
| <input type="checkbox"/> Information Disclosure Statement; Form PTO-1449 | <input type="checkbox"/> Statement under 37 CFR 3.73(b) |
| <input type="checkbox"/> Cited References | <input type="checkbox"/> Terminal Disclaimer |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> Request for Refund |
| <input type="checkbox"/> Response to Missing Parts under 37 C.F.R. 1.52 or 1.53 | |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application | |

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|---|
| <input type="checkbox"/> CD(s), Number of CD(s) _____ |
| <input type="checkbox"/> After Allowance Communication to Group |
| <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences |
| <input type="checkbox"/> Appeal Communication to Group (<i>Appeal Notice, Brief, Reply Brief</i>) |
| <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Status Letter |
| <input checked="" type="checkbox"/> Return Receipt Postcard |
| Additional Enclosure(s) (<i>please identify below</i>): |
| _____ |
| _____ |
| _____ |

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual Name	Richard G. Sharkey, Ph.D. Registration No. 32,629	Customer Number 00500
Signature		
Date	Aug 18, 2004	

VIA EXPRESS MAIL

MillicentS/509089



**RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE - EXAMINING GROUP 1640**

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TRANSMITTAL LETTER

Commissioner:

Further to the Reply and Amendment submitted on July 27, 2004, please find enclosed the Declaration executed by inventor Martin A. Cheever under 37 C.F.R. § 1.132.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

Richard G. Sharkey, Ph.D.
 Registration No. 32,629

Customer Number 00500

Enclosure:

Declaration of Martin A. Cheever under 37 C.F.R. § 1.132